

FORM PTO-1390
(REV. 11-2000)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

CHA216

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

09/936582

INTERNATIONAL APPLICATION NO.

PCT/FR00/00618

INTERNATIONAL FILING DATE

15 MARCH 2000

PRIORITY DATE CLAIMED

15 MARCH 1999

TITLE OF INVENTION

DEVICE FOR INOSCULATION OF A HOLLOW ORGAN TO THE SKIN

APPLICANT(S) FOR DO/EO/US

THIERRY SCHEYE

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☒ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.
14. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. ☒ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☐ Other items or information:

U.S. APPLICATION NO. 09/936582		INTERNATIONAL APPLICATION NO. PCT/FR00/00618		ATTORNEY'S DOCKET NUMBER C7A 216	
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21. <input checked="" type="checkbox"/> The following fees are submitted: BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)): Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO. \$1000.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO \$860.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$710.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$690.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00 ENTER APPROPRIATE BASIC FEE AMOUNT =				CALCULATIONS PTO USE ONLY <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;">\$ 860.00</div>	
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total claims	7 - 20 =		x \$18.00	\$	
Independent claims	/ - 3 =		x \$80.00	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$270.00	\$	
TOTAL OF ABOVE CALCULATIONS =				\$ 860.00	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$	
SUBTOTAL =				\$ 430.00	
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$	
TOTAL NATIONAL FEE =				\$ 430.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$	
TOTAL FEES ENCLOSED =				\$ 430.00	
				Amount to be refunded:	\$
				charged:	\$

a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.


c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 11-0224. A duplicate copy of this sheet is enclosed.

d. ☒ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Horst M. Kasper
13 Forest Drive
Warren, N.J. 07059


 SIGNATURE
HORST M. KASPER
 NAME
28,559
 REGISTRATION NUMBER

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Thierry Scheye

Serial No: Art Unit:

Filing Date:

Title: DEVICE FOR INOSCULATION OF A HOLLOW ORGAN TO THE SKIN

PCT No.: PCT/FR00/00618 Filing Date: 15 March 2000

Priority: No.: 99/03897 Filing Date: 15 March 1999 Country: France

September 13, 2001

Attorney's Docket No.: CHA216

PRELIMINARY AMENDMENT

Hon. Commissioner of Patents and Trademarks

Box PCT

Washington, D.C. 20231

SIR:

This is a preliminary amendment to provide certain corrections in the above captioned patent application. The applicant petitions that, if required, the time for response be extended and the corresponding fee be charged. The Commissioner is hereby authorized to charge any additional fees which may be required to Acct. No. 11-0224. The Applicant further respectfully requests that this response be accepted as a bona fide effort to meet any potential response requirements outstanding and due in the above captioned matter. Please amend the application as follows:

IN THE CLAIMS:

CLEAN VERSION OF THE AMENDED CLAIMS

3. Device according to claim 1, with the following characteristics:

The relative mobility between the two parts (2, 4) of the transparietal tube is obtained by screwing (26), with the distal part (4) of the tube being provided with a non circular axial opening (18) that constitutes the said nesting organ, in order for it to be rendered immobile in the rotational direction by the practitioner using a specific tool (16), that can be introduced inside the said axial opening (18) and that comprises at least one area of complementary cross-section;

4. Device according to claim 2, with the following characteristics:

The pusher (16) comprises between its two ends a non circular section designed to traverse the axial opening (18) of complementary shape in the distal part (6), in order to render the latter (6) immobile in the rotational direction;

5. Device according to claim 1, with the following characteristics:

the transparietal tube (2, 4) is "telescopic" and comprises at least two end parts (2, 4) making up the said distal (4) and proximal (2) parts of the tube;

6. Device according to claim 5, with the following characteristics:

the distal (4) and proximal (2) parts of the tube are connected one to the other by screwing (26);

7. Device according to claim 1, with the following characteristics:

the relative mobility between the parts (2, 4) of the tube is obtained by the parts (2, 4) sliding axially one relative to the other, with the distal part (4) of the tube being rendered immobile by means of a "bayonet" device (10, 12), with slots (10) being provided in the distal part (4) of the tube in order

to allow the latter to be gripped by a specific tool (14) provided with lugs
(12).

MARKED-UP VERSION OF THE AMENDED CLAIMS

(Version with markings to show changes made)

3. (amended) Device according to [any one of the preceding claims] claim 1, with the following characteristics:

The relative mobility between the two parts (2, 4) of the transparietal tube is obtained by screwing (26), with the distal part (4) of the tube being provided with a non circular axial opening (18) that constitutes the said nesting organ, in order for it to be rendered immobile in the rotational direction by the practitioner using a specific tool (16), that can be introduced inside the said axial opening (18) and that comprises at least one area of complementary cross-section;

4. (amended) Device according to [claims 2 and 3] claim 2, with the following characteristics:

The pusher (16) comprises between its two ends a non circular section designed to traverse the axial opening (18) of complementary shape

in the distal part (6), in order to render the latter (6) immobile in the rotational direction;

5. (amended) Device according to [any one of the preceding claims] claim 1, with the following characteristics:

the transparietal tube (2, 4) is "telescopic" and comprises at least two end parts (2, 4) making up the said distal (4) and proximal (2) parts of the tube;

6. (amended) Device according to [any one of claims 3 to 5] claim 5, with the following characteristics:

the distal (4) and proximal (2) parts of the tube are connected one to the other by screwing (26);

7. (amended) Device according to [any one of claims 1 and 2] claim 1, with the following characteristics:

the relative mobility between the parts (2, 4) of the tube is obtained by the parts (2, 4) sliding axially one relative to the other, with the distal part (4) of the tube being rendered immobile by means of a "bayonet" device (10, 12), with slots (10) being provided in the distal part (4) of the tube in order to allow the latter to be gripped by a specific tool (14) provided with lugs (12).

REMARKS

Claims 1 through 7 are in the case. Claims 3 through 7 are being amended.

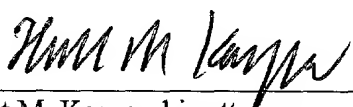
The present preliminary amendment is submitted in order to eliminate multiple dependencies between claims.

Should be there any multiple dependent claims remaining, such remaining multiple dependent claims are to be deemed as treated as canceled by the applicant.

Entry of the above-recited corrections prior to calculation of the fee is respectfully requested.

Respectfully submitted,

Thierry Scheye

By: 

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Attorney's Docket No.: CHA216

*%PAMEND(CHA216A1(September 13, 2001(tm-894

Inventor(s): Thierry Scheye

Title: DEVICE FOR INOSCULATION OF A HOLLOW ORGAN TO THE SKIN

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**ENGLISH LANGUAGE TRANSLATION OF INTERNATIONAL
PCT APPLICATION**

PCT Application no: PCT/FR00/00618
Filing Date: 15 March 2000

1/ptb

The invention comes under the field of medical instrumentation and concerns a device for inosculation of a hollow organ to the skin.

There is a known medical technique for inosculation of a hollow organ to the skin. This technique can be used for various organs such as the stomach, colon, small intestine or the bladder and uses a device designed to provide communication between the outside of the body and the inside of the organ. Generally speaking this kind of device comprises principally a transparietal tube with elements at each end, such as or similar to collars, that press respectively against the inside wall of the organ and the outer surface of the skin: these collars are termed respectively intravisceral and skin collars.

These devices can be divided into two types, the first being described, for example, by US4344435 (AUBIN), US5374254 (BUMA) and US5484420 (RUSSO), for which the distal end of the transparietal tube possesses a shoulder forming the intravisceral collar, with the other end of the tube designed to protrude from the patient's body and shaped to take the skin collar on the outside, whether this is screwed on (US4344435), clipped on (US5374254) or hard push fitted (US5484420),

for example. These devices are fitted on the patient either by introducing the tube via the oesophagus until the proximal end of the tube emerges from an incision in the patient's skin (US5374254) and (US5484420), or by making an incision in the patient's body large enough to allow the intravisceral collar to be introduced (US4344435).

The disadvantage with this first type of device is that surgery and anaesthesia are necessary for them to be installed. In addition they are more particularly designed to work with a specific fitting installed permanently for the whole period of treatment, and are uncomfortable for the patient notably because they protrude from the body at all times.

This is the reason why a second type of device was developed, the so-called "button", where almost the whole length of the tube lies within the wall of the body to avoid the discomfort of any protrusion. With most of these devices an opening is first made in the patient's body and allowed to heal, after which the intravisceral collar, the shape of which can be altered sufficiently to pass through the opening easily, can be introduced directly from the outside. The practitioner alters the shape of the intravisceral collar when installing the button, notably using a pusher that can be inserted inside the tube. Finally a shutter is often provided to

close the transparietal tube when not in use. This type of device is described notably in patents GB2169808 (HABERMAN) and US4325513 (NAWASH) and also in patent US5374254 referred to above, that has an arrangement to transform the first type of device into the second type, by cutting the tube after installation and closing it with a shutter.

A more general problem posed by the above-mentioned inosculation devices lies in the fact that the cumulated thickness of fascia crossed varies from one patient to another, and also according to where the device is installed on the patient, and even for the same place and same patient from one point in time to another; for example, in the case of gastrostomy when the patient gains weight during treatment this results in the abdominal wall growing thicker thus rendering inadequate the button installed at the outset.

Note that this problem is solved when devices of the first type are installed on the patient, thanks to the fact that the tube on which the skin collar is installed protrudes from the skin so that the collar can be adjusted as required on the patient, and even for devices US4344435 and US5484420, for which during treatment the screwed or sliding

connection of the collar on the tube can be adjusted and thus allow changes in the distance separating the two collars one from the other as required.

In order to overcome this problem for devices of the second type, sets of buttons have been proposed where the respective length of the tube varies, so that the practitioner chooses the one most suited to the case in hand. However this answer is not totally satisfactory because it may happen that none of the buttons available in the set has a tube length corresponding exactly to what is needed.

Buttons have also been proposed in which the collar that holds the tube against the inside wall of the organ and the shape of which can be modified, is balloon shaped to allow for a relative change in the distance separating the two collars one from the other. However in practice it has been found that the balloon, that is inflated with normal saline, tends to rupture especially if the patient moves abruptly, such as for example when coughing or when straining with the abdominal muscles due to constipation.

Finally there was another proposal, notably with patent GB2169808 (HABERMAN), to have a sliding fit for the intravisceral

collar on the transparietal tube, so that when the button is installed the intravisceral collar can be brought more or less close to the skin collar according to the patient in question, by means of traction on the intravisceral collar using pull threads. However, although this answer avoids the need of having to place a large number of collars in a set at the practitioners disposal, it does not allow the distance between the collars to be adjusted during treatment, notably to allow for the patient's weight gain. This function that is adjustable only when the device is installed on the patient is highlighted by the fact that the threads that are used to hold the intravisceral collar are designed to be either broken down by the gastric juices or to be resorbable. Finally it should be noted that contradictory functions are required of the means of connection between the intravisceral collar and the tube, because this connection has to be both rigid enough for satisfactory stability of the device on the patient and yet allow for slippage when the position of the intravisceral collar needs to be adjusted.

Generally speaking it can be seen that none of the devices of the first nor of the second type of device described above has any means of adjusting the distance separating the intravisceral and skin collars during

treatment, except for the configuration in which the transparietal tube protrudes from the patient's body to receive the skin collar and which is not comfortable for the patient. In other words, the second type of device, the so-called buttons, do not possess the said means of adjustment except for by using the same method as the first type of device, i.e. making the tube protrude from the patient's body, in which case this second type no longer complies with the criteria of comfort that prompted their design.

The device presented with this invention is a device for inosculation of a hollow organ to the skin, along the same lines as the second type of device described above, i.e. the so-called button, comprising a transparietal tube the ends of which are attached to collars that hold the tube respectively against the internal wall of the organ (intravisceral collar) and against the outside surface of the skin (skin collar), with the intravisceral collar designed so that its shape can be changed by the practitioner using notably a pusher, to allow it to pass inside the organ directly from outside the patient's body. Note that with these button type devices the axial dimension lies within that of the two intravisceral and skin collars in order to be comfortable for the patient. For example the intravisceral collar forms the base of a hollow body, the

shape of which is changed by the practitioner using a pusher that is introduced inside the tube, with the said hollow body comprising lateral openings so that liquids can pass through the liquids tube between the organ and the outside.

The purpose of the present invention is to offer a device of the type described above that can be installed and adapted for a given patient, according to the thickness of the walls involved, whilst ensuring that the patient's comfort is not affected by an awkward protrusion of the tube outside his body.

With the present invention, and based on the analysis above that contributes to the inventive approach to this invention, a device of the type described above comprises a transparietal tube made up of at least two parts, each attached respectively to the intravisceral and to the skin collar. These parts of the transparietal tube are fitted so as to be mobile for the relative change in axial position in a fashion that is not spontaneously reversible. The so-called distal part of the tube that is attached to the intravisceral collar has means of rendering it immobile working from the outside to the inside of the tube, so that the practitioner can make the said change in position. These arrangements are such that

the practitioner can adapt the length of the tube in both directions, according to the cumulated thickness of the fascia crossed in the patient, both at the time and after installation of the tube on the patient, and such that the variation in length of the tube is taken up in the thickness of the patient's fascia that it crosses, that is to say in other terms that the variation in the length of tube, notably with respect to lengthening, does not change the initial distance it protruded from the patient's body.

The result of these arrangements is that a variation in the distance between the intravisceral and skin retention collars is now possible, including after installation of the device on the patient, with the said variation being obtained by a deliberate procedure carried out by the practitioner and having no adverse effect, neither on the reliability of the device in place, nor on how comfortable it is for the patient.

It should be understood that according to various variations similar at this general stage of the invention, the said two proximal and distal parts of the transparietal tube are fitted so as to be mobile in coaxial fashion, either one upon the other or again each relative to an intermediary body.

In the case that the intravisceral collar is designed to have its shape changed by the practitioner using a pusher that is introduced inside the tube, the distal part of the tube is best designed in order to enable it to be gripped by the pusher to render it immobile, with this aspect of the design being for example of the bayonet type in the event that mobility of the parts of the tube relies upon sliding, or again by a non circular type of nesting fit for the pusher via the axial opening of the distal part of the tube, in the event that the mobility of the parts of the tube relies upon a screw action. These arrangements enable the practitioner to adapt the length of transparietal tube using the pusher, at least the initially when the tube is installed on the patient.

It should be understood that a pusher comprising arrangements that are complementary to those of the distal part of the tube for the said immobilisation of the latter, are part of the device covered by the invention.

The relative mobility between the two parts of the transparietal tube is preferably obtained by a screwing movement. The distal part of the tube is for example designed with a non circular axial opening that forms the said nesting organ, so that it can be immobilised in the

rotational direction by the practitioner using a specific tool. This tool can be introduced into the said axial opening of the distal part of the tube, and comprises at least one area of complementary cross-section.

In the preferred form for constructing the invention, the distal and proximal parts of the transparietal tube are connected one to the other by screwing, and advantage is taken of the pusher used to change the shape of the intravisceral collar to immobilise the distal part of the tube in the rotational direction. To this end the pusher, or a specific tool of the type described above, comprises for example a non circular section between its two ends designed to traverse the axial opening of complementary shape in the distal part of the tube.

With another approach to the invention, the transparietal tube is "telescopic". By "telescopic" should be understood in general the capacity conferred upon the transparietal tube to change its axial dimension. The tube comprises at least two end parts, each respectively attached to the intravisceral and skin collars, that are mobile in an axial direction one relative to the other in order to enable the length of the tube to be varied. The distal part at least, if not both parts of the tube, can be rendered immobile from the outside, notably using a tool designed to

grip the distal part of the tube to enable the practitioner to change the length of the tube, in both directions, after installing the device on the patient.

It will be more easy to understand the invention and the details concerning it in the description that is going to be made of a preferred form of construction, by referring to the drawings on the appended sheet, in which:

Fig. 1 is a diagrammatic view along the axis, of a device using a first form of construction for the invention, where the shape of the intravisceral collar is being changed by a pusher,

Fig. 2 is an axial view of a device according to a second type of construction for the invention, and is the preferred type,

Fig. 3 is a partial transverse section view of the device illustrated in the previous figure.

On these drawings, a device for inosculation of a hollow organ to the skin comprises principally a tube in two parts 2 and 4, each of these parts 2 and 4 being attached to a retention collar, 6 and 8, respectively against the internal wall of the organ for the distal part 4 of the tube, and against the external surface of the skin for the proximal part 2 of the tube.

The two parts 2 and 4 of the tube are mobile in an axial direction one relative to the other, with the possibility of rendering the distal part 4 of the tube immobile from the outside in order to enable the practitioner to vary the length of tube 2, 4, including when the device has been installed on the patient.

Note that a variation in the distance d separating the collars 6 and 8 one from the other is absorbed by a corresponding variation in the cumulated thickness of the fascia 1 of the patient crossed by tube 2, 4, with any variation in the said distance d inducing consequently a simultaneous variation of the length of the tube 2, 4 lying between the two collars 6 and 8.

On the variation illustrated in fig. 1, the relative mobility between parts 2 and 4 of the tube is obtained by parts 2 and 4 sliding axially one relative to the other. Immobilisation of the distal part 4 of the tube is obtained by means of a "bayonet" device 10, 12, with slots 10 being provided on the distal part 4 of the tube to allow the latter to be held by a specific tool 14 provided with lugs 12.

On the variation illustrated in fig. 2 the said relative mobility between parts 2 and 4 of the tube is obtained by screwing, by means of

the tapping 26, with parts 2 and 4 composing the transparietal tube being preferably two in number and being screwed one into the other.

Immobilisation of the distal part 4 of the tube is obtained by means of pusher 16 generally used by the practitioner to push the intravisceral collar 8 out of shape when installing the device on a patient.

By referring to fig. 3, it will be noted that immobilisation in the rotational direction of the distal part 4 of the tube is obtained thanks to the non circular shape of the axial opening 18 of the distal part 4 of, the latter being traversed by an area of the pusher 18 having a cross-section of complementary shape.

It will be understood that having the transparietal tube in two parts 2 and 4 as illustrated in fig. 2 is a preference only, and that in equivalent manner the transparietal tube could include an intermediate part in addition, such as 20 on the example illustrated in fig. 1, without escaping the general rule of the invention described.

The device covered by the invention is preferably provided, in similar fashion to previous devices for this purpose, with a spontaneously closing valve 22 on the distal end of the tube, and a movable shutter 24 on the proximal end of the tube. Note also the presence as usual in this

context, of lateral openings 28 made in the hollow body forming intravisceral collar 8.

Note also that immobilisation of the proximal part 2 of the tube can be obtained using the skin collar 6, that can be easily gripped from outside.

In addition, the distal part 4 of the tube can be held to advantage from the inside of the transparietal tube using a removable instrument, such as 14 or 16 in the manner illustrated, to enable the distal part 4 of the tube to be held immobile by the practitioner without the said tool 14 or 16 protruding unpleasantly from the patient's body on a permanent basis.

As an indication, the proportional variation in the distance separating the two collars one from the other is of the order of 0.5 to 1 times the minimal length of the tube, depending on the size of the latter. For example, for a tube with minimum length 1 cm, the maximum length of the tube will be about 1.5 cm; for a tube measuring a minimum length of 3 cm, the maximum length of the tube will be about 6 cm.

Note finally that the applications for the device covered by the invention are not limited to human surgery, but can be used also for veterinary surgery.

CLAIMS

1. Device for inosculation of a hollow organ to the skin, of the type of device comprising a transparietal tube, the ends of which are attached to collars (6, 8) holding the tube, respectively, against the internal wall of the organ (intravisceral collar 8) and against the outside surface of the skin (skin collar 6), with the intravisceral collar (8) being designed so that its shape can be changed by the practitioner to allow the intravisceral collar (8) to pass inside the organ directly from the outside of the patient's body, with the following characteristics:

The transparietal tube comprises at least two parts (2, 4), each attached to a collar respectively intravisceral (8) and skin (6), the said parts (2, 4) of the tube being fitted so that they are mobile for relative changes axial in position that are not spontaneously reversible, the said distal part (4) of the tube, attached to the intravisceral collar (8), comprising means of immobilisation (10, 12, 26) that can be used from the outside towards the inside of the tube to enable the practitioner to make the said changes in position,

Such that the practitioner can adapt the length of the tube (2, 4),

in both directions, according to the cumulated thickness of the fascia (1) of the patient crossed, both at the time and after the tube (2, 4) is installed on the patient, and such that the variation in the length of the tube is taken up inside the thickness of the fascia (1) of the patient that it crosses;

2. Device according to claim 1, where the shape of the intravisceral collar (8) can be changed by the practitioner by means of a pusher (16) that can be introduced inside the tube (2, 4), with the following characteristics:

The distal part (4) of the tube is specially designed to enable it to be gripped by the pusher (16) in order to render it immobile,

Such that the practitioner can adapt the length of transparietal tube (2, 4) using the pusher (16) at least initially when the tube (2, 4) is installed on the patient;

3. Device according to any one of the preceding claims, with the following characteristics:

The relative mobility between the two parts (2, 4) of the transparietal tube is obtained by screwing (26), with the distal part (4)

of the tube being provided with a non circular axial opening (18) that constitutes the said nesting organ, in order for it to be rendered immobile in the rotational direction by the practitioner using a specific tool (16), that can be introduced inside the said axial opening (18) and that comprises at least one area of complementary cross-section;

4. Device according to claims 2 and 3, with the following characteristics:

The pusher (16) comprises between its two ends a non circular section designed to traverse the axial opening (18) of complementary shape in the distal part (6), in order to render the latter (6) immobile in the rotational direction;

5. Device according to any one of the preceding claims, with the following characteristics:

the transparietal tube (2, 4) is "telescopic" and comprises at least two end parts (2, 4) making up the said distal (4) and proximal (2) parts of the tube;

6. Device according to any one of claims 3 to 5, with the following characteristics:

the distal (4) and proximal (2) parts of the tube are connected one to the other by screwing (26);

7. Device according to any one of claims 1 and 2, with the following characteristics:

the relative mobility between the parts (2, 4) of the tube is obtained by the parts (2, 4) sliding axially one relative to the other, with the distal part (4) of the tube being rendered immobile by means of a "bayonet" device (10, 12), with slots (10) being provided in the distal part (4) of the tube in order to allow the latter to be gripped by a specific tool (14) provided with lugs (12).

WO 00/54727

PCT/FR00/00618

1 / 1

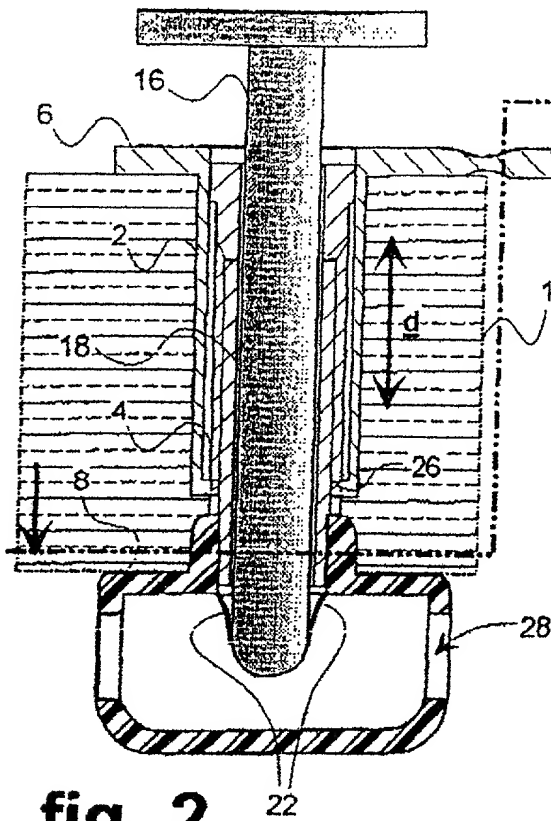


fig. 2

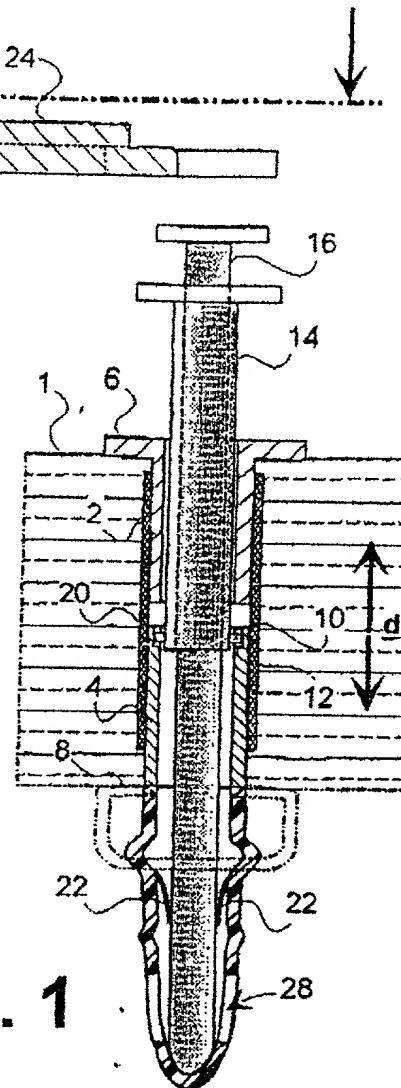


fig. 1

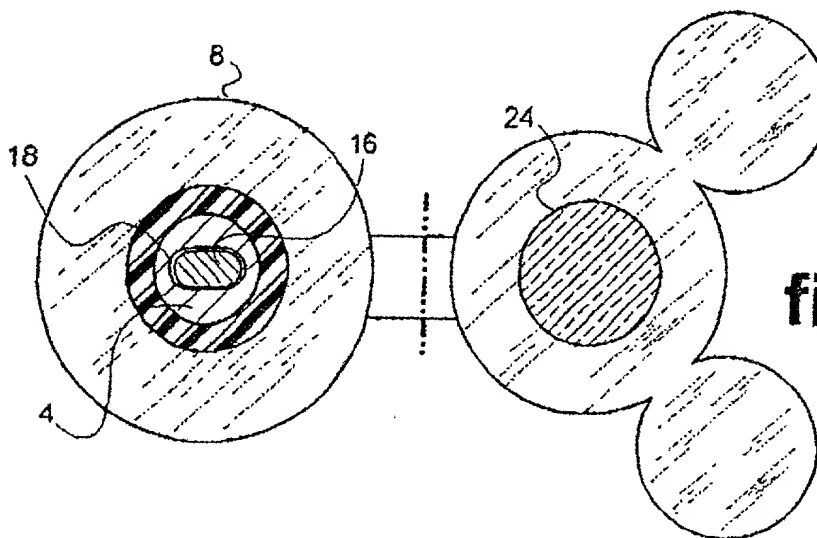


fig. 3

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION**Déclaration et Pouvoirs pour Demande de Brevet****French Language Declaration**

En tant qu'inventeur nommé ci-après, je déclare par le présent acte que:

As a below named inventor, I hereby declare that:

Mon domicile, mon adresse postale et ma nationalité sont ceux figurant ci-dessous à côté de mon nom.

My residence, post office address and citizenship are as stated below next to my name.

Je je crois être le premier l'inventeur original et unique (si un seul nom est mentionné ci-dessous), ou l'un des premiers co-inventeurs originaux (si plusieurs noms sont mentionnés ci-dessous) de l'objet revendiqué, pour lequel une demande de brevet a été déposée concernant l'invention intitulée: **DISPOSITIF D'ABOUCHEMENT D'UN VISCERE CREUX A LA PEUX.**

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: **DEVICE FOR INOSCULATION OF A HOLLOW ORGAN TO THE SKIN**

et dont la description est fournie ci-joint moins que la case suivante n'ait été cochée.

the specification of which is attached hereto unless the following box is check (check only one item below)

☒ a été déposée le 15 mars 2000 sous le numéro de demande des États-Unis ou le numéro de demande internationale PCT, PCT/FR00/00618 et modifiée le _____ (le cas échéant).

was filed on March 15, 2000 as United States Application No or PCT International Application Number PCT/FR00/00618 and was amended on _____ (if applicable).

Je déclare par le présent acte avoir passé en revue et compris le contenu de la description ci-dessus, revendications comprises, telles que modifiées par toute modification dont il aura été fait référence ci-dessus.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

Je reconnais devoir divulguer toute information pertinente à la brevetabilité, comme défini dans le Titre 37, §1.56 du Code fédéral des réglementations.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

Je revendique par le présent acte avoir la priorité étrangère, en vertu du Titre 35, § 119(a)-(d) ou § 365(b) du Code des États-Unis, sur toute demande étrangère de brevet ou certificat d'inventeur ou, en vertu du Titre 35, § 365(a) du même code, sur toute demande internationale PCT désignant au moins un pays autre que les États-Unis et figurant ci-dessous et, en cochant la case, j'ai aussi indiqué ci-dessous toute demande étrangère de brevet, toute certificat d'inventeur ou toute demande internationale PCT ayant une date de dépôt précédant celle de la demande à propos de laquelle une priorité est revendiquée.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) or § 365(b) on any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which

designated at least one country other than the United States, listed below, and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT International application having a filing date before that of the application on which priority is claimed

**PRIOR FOREIGN APPLICATIONS
CLAIMED**

PRIORITY

DEMANDE(S) DE BREVET ANTÉRIEURE(S)

DROIT DE PRIORITÉ REVENDIQUÉ

99/03897

France

15/03/1999

<X>

(Number)
(Numéro)

(Country)
(Pays)

(Day/Month/Year Filed)
(Jour/Mois/Année de dépôt)

Je revendique par le présent acte toute bénéfice, en vertu du Titre 35 § 119(e) du Code des États-Unis, de toute demande de brevet provisoire effectuée aux États-Unis et figurant ci-dessous.

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below.

<>

(Application No.)
(N^o de demande)

(Filing Date)
(Date de dépôt)

Je revendique par le présent acte toute bénéfice, en vertu du Titre 35 § 120 du Code des États-Unis, de toute demande de brevet effectuée aux États-Unis, ou en vertu du Titre 35, § 365(c) du même Code, de toute demande internationale PCT désignant les États-Unis et figurant ci-dessous et, dans la mesure où l'objet de chacune des revendications de cette demande de brevet n'est pas divulgué dans la demande antérieure américaine ou internationale PCT en vertu des dispositions du premier paragraphe du Titre 35, § 112 du Code des États-Unis, je reconnais devoir divulguer toute information pertinente à la brevetabilité, comme défini dans le Titre 37, § 1.56 du Code fédéral des réglementations, dont j'ai pu disposer entre la date de dépôt de la demande antérieure et la date de dépôt de la demande nationale ou internationale PCT de la présente demande:

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s), or §365(c) of any PCT International application designating the United States, listed and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

<>

Appl. No.
N^o de demande

Filing Date
Date de dépôt

Status (patented, pending, abandoned)
Statut (breveté, en cours d'examen, abandonné)

Je déclare par le présente acte que toute déclaration ci-incluse est, à ma connaissance, véridique et que toute déclaration formulée à partir de renseignements ou de suppositions est tenue pour véridique; et de plus, que toutes ces déclarations ont été formulées en sachant que toute fausse déclaration volontaire ou son équivalent est passible d'une amende ou d'une incarcération, ou des deux, en vertu de la Section 1001 du Titre 18 du code des États-Unis, et que de telles déclarations volontairement fausses risquent de compromettre la validité de la demande de brevet ou du brevet délivré à partir de celle-ci.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

POUVOIRS: En tant qu'inventeur cité, je désigne par la présente l'(les) avocat(s) et/ou agent(s) suivant(s) pour qu'ils poursuive(nt) la procédure de cette demande de brevet et traite(nt) toute affaire s'y rapportant avec l'Office des brevets et des marques: (*mentionner le nom et le numéro d'enregistrement*).

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (*list name and registration number*)

2
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Full name of sole or first inventor: **Thierry Scheye**

Signature de l'inventeur

Inventor's signature

Date

Date

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